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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,053	10/14/2003	Michael E. Jolley	02-1106-A	7002

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,053	JOLLEY ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 14-20* is/are pending in the application.

4a) Of the above claim(s) *14-18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-8 and 19 filed on August 28, 2006 is acknowledged. Claims 9-13 have been cancelled. Claims 14-18 and 20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

The traversal is on the grounds that Groups I and III would not require separate searches. Applicant urges that the Examiner has not set forth an example as to how the assay kit can be used in a manner different from the recited method of detecting *Salmonella* antigen in the claims. These arguments have been fully considered but are not found to be persuasive for the reasons below:

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct patented inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01). In the instant situation, the inventions of Groups I and III are drawn to distinct

inventions which are separate products and methods capable of separate manufacture, use or sale as described in the previous Office Action.

Classification of the subject matter is merely one indication of the burdensome nature of the search. The literature search, particularly relevant in this art, is not co-extensive, because for example, Group III is drawn to products. Groups III are drawn to different methods which require different method steps, parameters and endpoints. Clearly different searches and issues are involved in the examination of each Group.

To address Applicant's arguments regarding other uses for the assay kit, the assay kit can be used to purify antigens in affinity purification.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Specification

2. The use of trademarks has been noted in this application. See for example, page 7, Sentry-FP™. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Applicant is asked to review the specification for various trademarks and appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Both sets of claims recite a method of detecting antibodies to bacterial antigens. Claim 1 of U.S. Patent No 5,976, 820 recites "a method of detecting antibodies to a bacterial O-antigen present in a fluid comprising combining a fluid which may contain antibodies to bacterial antigen with a fluorophore-conjugated oligosaccharide antigen and measuring the extent of formation of immune complex by comparing the fluorescence polarization value after complex formation to a negative control value". The instant claims recite a "method of detecting *Salmonella* in a sample, said method comprising the steps of: combining said sample with a tracer and an anti-*Salmonella* antibody to form an assay mixture, said tracer comprising a fluorophore conjugated to an oligosaccharide from a *Salmonella* cell wall lipopolysaccharide, said tracer being to

bind to said anti-*Salmonella* antibody to produce a detectable change in fluorescence polarization and measuring the fluorescence polarization of said assay mixture to obtain a measured fluorescence polarization value, wherein said measured fluorescence polarization value is related to the concentration of *Salmonella* antigens in said sample".

The method of U.S. Patent No 5,976, 820 recites detecting bacterial antigen and the claimed method recites detecting *Salmonella* antigen. Thus, U.S. Patent No 5,976, 820 encompasses a method of detecting a genus of bacterial antigens and the instant claims encompass a method of detecting a species of bacterial antigens *(Salmonella)*. Therefore, the two sets of claims overlap in scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1-8 and 19 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what Applicant intends by "detectable change". Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-8 and 19 are rejected under 35 U.S.C. 102(a) as anticipated by Gast et al *(Avian Diseases 46:137-142, Jan-Mar 2002).*

Claims 1, 3-8 and 19 are drawn to a method of detecting *Salmonella* in a sample, said method comprising the steps of: combining said sample with a tracer and an anti-*Salmonella* antibody to form an assay mixture, said tracer comprising a fluorophore conjugated to an oligosaccharide from a *Salmonella* cell wall lipopolysaccharide, said tracer being to bind to said anti-*Salmonella* antibody to produce a detectable change in fluorescence polarization and measuring the fluorescence polarization of said assay mixture to obtain a measured fluorescence polarization value, wherein said measured fluorescence polarization value is related to the concentration of *Salmonella* antigens in said sample.

Gast et al teach a method of detecting *Salmonella* antigens in fecal samples and serum samples using fluorescence polarization and enzyme immunoassay (see the Abstract). Gast et al teach that the study evaluated the detection of antibodies in the sera of experimentally infected chickens by a fluorescence polarization assay with a

tracer prepared from the O-polysaccharide of *S. enteriditis* an enzyme-linked immunosorbent assay (ELISA) with an *S. enteriditis* flagellin antigen (see the Abstract).

Gast et al anticipate the claimed invention.

6. Claims 1-4, 6-8 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by Nasir et al, *Detection of Salmonella Enteritidis Infections in Chickens and Egg Yolks Using Fluorescence Polarization*, Proceedings of the One Hundred and Fourth Annual Meeting of the United States Animal Health Association, Birmingham, Alabama, October 20-27, 2000).

Claims 1-4, 6-8 and 19 are drawn to a method of detecting *Salmonella* in a sample, said method comprising the steps of: combining said sample with a tracer and an anti-*Salmonella* antibody to form an assay mixture, said tracer comprising a fluorophore conjugated to an oligosaccharide from a *Salmonella* cell wall lipopolysaccharide, said tracer being to bind to said anti-*Salmonella* antibody to produce a detectable change in fluorescence polarization and measuring the fluorescence polarization of said assay mixture to obtain a measured fluorescence polarization value, wherein said measured fluorescence polarization value is related to the concentration of *Salmonella* antigens in said sample.

Nasir et al method of detecting *Salmonella* antibodies in chickens (see the Abstract). Nasir et al teach that the O-polysaccharide (OPS) from *Salmonella enteritidis* was prepared from commercially available lipopolysaccharide (LPS) by acid hydrolysis and labeled with fluorescein to give a fluorophore (tracer) specific for *Salmonella*

enteritidis (see the Abstract). Nasir et al teach that fluorescein isothiocyanate isomer was used in the assay (Materials and Methods section, section 2). Nasir et al teach that sera samples (cultured samples) and egg yolks (food product) were used in the assay (Materials and Methods section, section 2.5). Nasir et al teach the method steps of combining the tracer with the anti-*Salmonella* antibody and the tracer is fluorophore conjugated to OPS (see the Abstract). Nasir et al teach that the fluorescence polarization is measured (see the Abstract). Nasir et al teach that the assay can be used to eliminate bacteria from the food supply (Introduction, section 1). Nasir et al teach that buffer and blank serum reading were taken (see the Abstract). Nasir et al anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-8 and 19 are rejected under 35 U.S.C. 103(a) as unpatentable over Nasir et al, *Detection of Salmonella Enteritidis Infections in Chickens and Egg Yolks Using Fluorescence Polarization*, Proceedings of the One Hundred and Fourth Annual Meeting of the United States Animal Health Association, Birmingham, Alabama, October 20-27, 2000) in view of Gast et al *(Avian Diseases 46:137-142, Jan-Mar 2002).*

Claims 1-8 and 19 are drawn to a method of detecting *Salmonella* in a sample, said method comprising the steps of: combining said sample with a tracer and an anti-*Salmonella* antibody to form an assay mixture, said tracer comprising a fluorophore conjugated to an oligosaccharide from a *Salmonella* cell wall lipopolysaccharide, said tracer being to bind to said anti-*Salmonella* antibody to produce a detectable change in fluorescence polarization and measuring the fluorescence polarization of said assay mixture to obtain a measured fluorescence polarization value, wherein said measured fluorescence polarization value is related to the concentration of *Salmonella* antigens in said sample.

Nasir et al teach a method of detecting *Salmonella* antibodies in chickens (see the Abstract). Nasir et al teach that the O-polysaccharide (OPS) from *Salmonella enteritidis* was prepared from commercially available lipopolysaccharide (LPS) by acid hydrolysis and labeled with fluorescein to give a fluorophore (tracer) specific for *Salmonella enteritidis* (see the Abstract). Nasir et al teach that fluorescein isothiocyanate isomer was used in the assay (Materials and Methods section, section 2). Nasir et al teach that sera samples and egg yolks (food product) were used in the assay (Materials and Methods section, section 2.5). Nasir et al teach the method steps of combining the tracer with the anti-Salmonella antibody and the tracer is fluorophore conjugated to OPS (see the Abstract). Nasir et al teach that the fluorescence polarization is measured (see the Abstract). Nasir et al teach that the assay can be used to eliminate bacteria from the food supply (Introduction, section 1). Nasir et al teach that buffer and blank serum reading were taken (see the Abstract).

Nasir et al do not teach the claim limitation "wherein said sample is from animal feces".

Gast et al teach a method of detecting *Salmonella* antigen in fecal samples and serum samples using fluorescence polarization and enzyme immunoassay (see the Abstract). Gast et al teach that the study evaluated the detection of antibodies in the sera of experimentally infected chickens by a fluorescence polarization assay with a tracer prepared from the O-polysaccharide of *S. enteriditis* an enzyme-linked immunosorbent assay (ELISA) with an *S. enteriditis* flagellin antigen (see the Abstract).

It would be *prima facie* obvious at the time the invention was made to modify the method of Nasir et al to evaluate antibodies in fecal samples because Gast et al has demonstrated that *Salmonella* antibodies can be detected in fecal samples and serum samples using fluorescence polarization and enzyme immunoassay. It would be expected barring evidence to the contrary, fluorescence polarization is an effective method of detecting antibodies in fecal samples.

Status of Claims

8. No claims are allowed.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571.272.0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vanessa L. Ford
Biotechnology Patent Examiner
November 21, 2006

NITA MINNIFIELD
PRIMARY EXAMINER